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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,010	02/27/2002	Jason A. Galdonik	293/045 CIP	8588

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EXAMINER

ROBERTS, PAUL A

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 01/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/084,010

Applicant(s)

GALDONIK ET AL.

Examiner

Paul A Roberts

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Objections*

1. The claims contain multiple occurrences of the use of an article immediately preceding a gerund. The use of this type of language is nonstandard and serves only to obfuscate the claimed subject matter. For example, in claim 3 line 2 the word *the* should be deleted. In claim 4, line 5 the word *inserting* should be deleted and "insertion of" inserted in its place. Appropriate correction required.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Shennib et al. US 6,464,709. Shennib et al. discloses a method for inserting the anastomosis device to complete a side-to-side anastomosis. Shennib et al. discloses that this device may be used to construct a surgical bypass (line 22, col. 1.) As shown in figure 2, described in column 9, lines 45-65, and described in column 10, lines 5-20, the method of inserting the Shennib et al. device includes making an aperture in the side wall of the graft vessel and the body vessel as well as making an incision proximal to item 50 in figure 2. The Shennib et al. device is hollow and annular and is inserted between the 1<sup>st</sup> and 3<sup>rd</sup> apertures. The method further includes inserting the 1<sup>st</sup>

Art Unit: 3731

connector through the 1<sup>st</sup> severed end and positioning the connector into the first aperture, wherein a 1<sup>st</sup> axial portion (2, figure 2) is extended from the 1<sup>st</sup> aperture. The first axial portion would be shielded by the surgeon's hand during an insertion of the Shennib et al. device. During the steps of moving, extending, and inserting, the first axial member is shielded by the surgeon's hand. The first axial portion is then unshielded when the surgeon removes his hand from the surgical site (after the anastomosis device is implanted.) The Shennib et al. method also includes the step of deforming the first connector thereby causing it to press together the sidewall of the graft conduit annularly and the sidewall of the body tissue conduit annularly. Shennib et al. specifies that it maybe necessary to annularly enlarge the connector using a balloon, which includes the steps of inflating and deflating the balloon (line 67, column 10.) Furthermore, Shennib et al. discloses the step of closing the graft conduit (65, col. 10.)

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shennib et al. '709 in view of Goldsteen et al. 5,976,179. Shennib et al. disclose all the limitations of claims 10-15 except Shennib et al. do not specifically point out how the bypass surgery would be implemented. It is well known in the art that an anastomosis device can be used as part of a surgical method to form a bypass. Goldsteen et al. shows in figure 32, a way to form a surgical

Art Unit: 3731

bypass of a blood clot using an anastomosis device. At the time of the invention it would have been obvious to one of ordinary skill in art to repeat the method in the Shennib et al. reference to construct a clot bypass as shown in the Goldsteen et al. reference.

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.


US 6,419,681, 5,254,127, 6,309,416, 5,234,447, 5,207,695 disclose various methods of suturing a graft to a vessel, including pneumatic means and protrusions within the device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A Roberts whose telephone number is (703) 305-7558. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Paul Roberts  
January 14, 2003

  
**MICHAEL J. MILANO**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 3700**